1035 Ultrasound and Doppler Guidance of Stenting

Monday, March 30, 1998, Noon–2:00 p.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: Noon–1:00 p.m.

1035-59 The 3-D Imaging Catheter in the Assessment of Stent Deployment

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Background: Atheromatous plaque causes complex 3-D deformation of the coronary artery lumen Coronary angiography and intravascular ultrasound are 2-D formats with significant limitations. The prototype 3-D Imaging catheter uses a balloon polymer with "deformation memory" to provide a 3-D luminal cast, which may be stored or removed by stretching to re-use of the catheter.

Methods: We have studied the catheter in simple tube and stenotic phantoms of diameter range 1.5 to 4.0 mm and examined its' utility in assessing stent deployment. Ninety six inflations (1.4 bar for 20 seconds at 370°C) in 12 phantoms were examined. The moulds were re-inflated to 0.34 bar and measured after 8 rotations each using macro-photography and callipers.

	Accuracy	Precision	Absolute error
Diameter 1.5–2.0	0.55 mm	0.23 mm	0.55 mm
Diameter 2.5–4.0	0.01 mm	0.06 mm	0.05 mm
Diameter stenosis	-1.15%	0.86%	1.21%
Lesion length	0.20 mm	0.60 mm	0.41 mm

Results: Systematic error was found with lumen diameters ≤2.0 mm. An accurate working range was identified between 2.5 and 4.0 mm (see table). Deployed stents could be visualised due to strut indentations.

Conclusion: The prototype 3-D Imaging Catheter accurately measures lumens in phantoms of 2.5 to 4.0 mm, and is a promising technique to assess lesion morphology and stent deployment.

1035-60 Incremental Value of IVUS After Coronary Stenting When a "perfect" Angiographic Result Is Obtained

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Restenosis and target vessel revascularization after stenting have been shown to strongly relate to the minimal stent diameter (MSD) and min. stent area (MSA) achieved by IVUS measurement. Whether IVUS adds incremental information regarding the adequacy of stent expansion if an excellent angiographic result is obtained is unknown. In the prospective OSTI-1 trial, 234 simultaneous paired QCA and IVUS coronary stent measures were acquired after JJIS stent implantation at varying pressures (12–22 atm.), and analyzed at independent core laboratories. By QCA, a diameter stenosis (DS) ≤0% was achieved in 76 stents (32%). QCA and IVUS measures, and the likelihood of achieving frequently used IVUS criteria for optimal stent implantation appear in the table for each group:

	QCA DS ≤ 0% (n = 76)	QCA DS > 0% (n = 158)	p value
QCA MSD	3.12 ± 0.53	2.70 ± 0.53	<0.0001
QCA diameter stenosis	10.7% ± 9.7	18.6% ± 11.8	<0.0001
IVUS measure or criteria			
MSD (mm)	3.00 ± 0.48	2.90 ± 0.48	NS
MSA (mm²)	8.29 ± 2.37	7.81 ± 2.39	NS
MSA > 90% avg. ref. CSA	42.7%	42.5%	NS
MSA > 100% dist ref CSA	46.7%	45.9%	NS
MSA > 70% balloon CSA	73.3%	77.3%	NS
MSA > 9 mm²	41.3%	33.3%	NS
MUSIC criteria	65.3%	56.5%	NS

ref. = reference segment; CSA = cross sectional area

Conclusions: There is little correlation between an optimal angiographic and IVUS stent result. When a "perfect" result is obtained by QCA (DS ≤ 0%), IVUS frequently reveals stent underdeployment, and conversely, stents may be well deployed by IVUS despite a less than perfect angiographic appearance. IVUS offers information complementary to QCA in the assessment of optimal stent deployment.

1035-61 Mechanistic Comparison of Rotational Atherectomy and Excimer Laser Angioplasty in the Treatment of In-stent Restenosis: A Volumetric Intravascular Ultrasound Study

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Both rotational atherectomy (RA) and excimer laser coronary angioplasty (ELCA) are used to treat restenosis within Palmaz-Schatz stents. To compare the mechanism and tissue ablation efficiency of these two techniques, we performed volumetric (vol) intravascular ultrasound analysis (IVUS: measurement of stent, lumen, and intimal hyperplasia (IH)) pre-intervention, after RA or ELCA, and after adjunct PTCA in 41 stents in 30 lesions. *Ablation efficiency* was calculated as the lumen volume post-RA or post-ELCA divided by the theoretical maximum achievable lumen volume (cross-sectional area of the RA or ELCA catheter × IH length).

	RA	ELCA	p
Pre- stent volume (mm³)	145 ± 29	155 ± 44	0.3933
Pre- lumen volume (mm³)	35 ± 25	46 ± 21	0.1521
Pre- IH volume (mm³)	110 ± 31	109 ± 34	0.9734
Δ lumen vol post-ablation (mm³)	34 ± 15	17 ± 9	<0.0001
ΔIH vol post-ablation (mm³)	34 ± 14	17 ± 10	<0.0001
Ablation efficiency (%)	90 ± 10	76 ± 15	0.0042
Final lumen volume (mm³)	115 ± 15	121 ± 28	0.3785

Catheter sizes were similar (RA: 1.97 ± 0.10 vs ELCA: 1.93 ± 0.13). There was a greater contribution of tissue ablation to overall lumen enlargement after RA than after ELCA (41 ± 15% vs 24 ± 16%, p = 0.0016). Additional stent expansion/IH extrusion during adjunct PTCA contributed more to overall lumen enlargement post-ELCA vs post-RA (75 ± 14% vs 63 ± 14% p = 0.0127).

We Conclude: Volumetric IVUS analysis shows that RA results in more tissue ablation compared to ELCA because of a greater ablation efficiency. Conversely, to achieve the same final lumen vol, a greater amount of additional stent expansion/IH extrusion during adjunct PTCA was necessary after ELCA.

1035-62 Restenosis After Intracoronary Ultrasound-guided Stent Deployment; A Randomized Multicentric Study. Results on the 6 Month Angiographic Restenosis Rate

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The benefit of intravascular ultrasound (ICUS) guidance as compared to the angiographic approach in stent implantation remains unclear upon 6 month restenosis rate. Assuming that a >50% reduction of restenosis rate would be clinically relevant, we randomized 155 pts in 2 groups, with (group A) and without (group B) ICUS guidance.

Optimal stent deployment was defined as cross sectional area within the stent >80% of the average cross-sectional area of proximal and distal reference segment. In group A, overdilatations were carried out when ICUS criteria was not reached. In group B, blinded ICUS was performed. In group A, 37/79 (39%) pts were submitted to ICUS-guided overdilatation without major complication. Angiographic 6 month follow-up was available in 144/155 (93%) pts. Overall restenosis rate was 26% (37/144), with a non significant difference between the 2 groups, 23% (16/71) in group A versus 29% (21/73) in group B.

We conclude that ICUS guidance, with our ICUS criterion, for adequate stent deployment, lead to a 25%, non significant, reduction in 6 month angiographic restenosis rate.

	Group A (n = 71)	Group B (n = 73)	p
MLD pre-PTCA	0.96 ± 0.37	1.02 ± 0.44	0.39
% stenosis pre-PTCA	65 ± 11	64 ± 12	0.51
MLD post-stenting	2.57 ± 0.4	2.46 ± 0.46	0.07
% stenosis post-stenting	16 ± 10	19 ± 9	0.35
MLD at FU	1.69 ± 0.64	1.[illegible] ± 0.65	0.41
% stenosis at FU	38 ± 20	42 ± 18	0.26
>50% stenosis	22.5% (16/73)	28.8% (21/71)	0.39

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